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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/563,024

12/30/2005

Dan Akerfeldt

030481-0251

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EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/563,024 | Applicant(s) AKERFELDT ET AL. | |
| | Examiner Eric Blatt | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Acknowledgement is made of the amendment filed January 15, 2008 amending claims 1-18 adding new claims 19-23.

Response to Arguments

Applicant's arguments filed January 15, 2008 have been fully considered but they are not persuasive. Applicant argues that Van Tassel et al. (US 6,949,113) and Torgerson et al. (US 6,361,551) are directed toward different applications than Applicant's invention, and thus are not properly combined with Akerfeldt et al. (WO 00/78226). Although Applicant correctly states that Van Tassel is directed to a device inserted into an atrial appendage and Torgerson is directed primarily to a process for making collagen fibers to prepare haemostatic fabrics to control bleeding, both Van Tassel and Torgerson teach that substances having haemostatic properties are useful for controlling bleeding, and these teachings are quite relevant to the vessel wall sealing device disclosed in Akerfeldt. The combinations of the haemostatic materials of Van Tassel and Torgerson with the sealing device of Akerfeldt are therefore appropriate.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 4, 6, 8, and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Said claims positively claim a portion of a human being, specifically a vessel wall. The Examiner suggests amending said claims to recite that the element is *configured to* be positioned against a vessel wall.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 15, 16, and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (WO 00/78226) in view of Van Tassel et al. (US 6,949,113).

Regarding claims 1-9, 15, 16, and 19-23, Akerfeldt discloses a method and device (Figures 1-2) for sealing a puncture in a vessel, comprising a sealing element 2 configured to be placed against a wall of the vessel and to seal the puncture in the vessel by contacting the vessel wall, an outer member 3 configured to be placed outside of the vessel. Akerfeldt additionally discloses an elongated member comprising at least suture 6 and longitudinally extending post 7. The elongated member 6, 7 is configured to extend in an incision canal leading to the puncture in the vessel and hold together the sealing element and the outer member. Outer member 3 comprises a locking element 3 connected to the elongated member and adapted to be positioned against an outer surface of the vessel wall, and the sealing element is in the form of a plug. The inner member 2 comprises an anchor member 2 connected to the elongated member 6, 7. The

outer member 3 comprises a second sealing element 3 having saw-teeth that fit into corresponding recesses on a portion of the elongated member 6, 7 that extends through the second sealing element 3.

Akerfeldt does not disclose the elongated member, plug, and locking element/second sealing element comprise a haemostatic material. Van Tassel discloses that it is old and well known to have closure devices designed to seal blood vessel walls comprise a haemostatic material. (Column 12, Lines 21-23) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by having the elongated member, the plug, and the locking element comprise a haemostatic material for purposes such as encouraging blood to coagulate, thereby preventing the vessel from leaking. So modified, said elements are configured to introduce haemostatic material into the incision canal to reduce secondary bleeding into the incision canal.

Akerfeldt does not disclose that the elongated member having a diameter that is small, less than 25%, preferably less than 10%, in comparison to the diameter of the sealing element. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dimensions of the elongated member and the sealing element since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1-4, 6, 8, and 10-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (WO 00/78226) in view of Torgerson et al. (US 6,361,551).

Regarding claims 1-4, 6, 8, and 10-23, Akerfeldt teaches all elements of said claims as previously discussed except that the elongated member comprises a haemostatic material such that the haemostatic material is a core of the elongated member (Claim 10), the elongated member is coated with the haemostatic material (Claim 11), the elongated member is impregnated or soaked with the haemostatic material (claim 12), or the elongated member is a multifilament comprising several filaments, each of which is coated with the haemostatic material (Claim 13). Akerfeldt additionally does not disclose that the haemostatic material is collagen. Torgerson discloses a fiber (elongated member) wherein the elongated member comprises a haemostatic material (Columns 1-3), the haemostatic material is a core of the elongated member (the whole fiber is haemostatic material, thus the core is haemostatic material), the elongated member is coated with the haemostatic material (Columns 1-3), the elongated member is impregnated or soaked with the haemostatic material (Columns 1-3), and the elongated member is a multifilament comprising several filaments, each of which is coated with the haemostatic material (Columns 1-3, Column 13, Lines 14-15). Additionally, Torgerson discloses that said haemostatic material is collagen.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by substituting the fiber disclosed in Torgerson for the elongated member 10 for purposes such as encouraging blood to coagulate, thereby preventing the vessel wall from leaking.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Eric Blatt
571-272-9735